

106TH CONGRESS
1ST SESSION

S. 1542

To amend the Federal Food, Drug, and Cosmetic Act to require any person who reprocesses a medical device to comply with certain safety requirements, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 5, 1999

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require any person who reprocesses a medical device to comply with certain safety requirements, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This title may be cited as the “Reprocessed Single
5 Use Medical Device Patient Safety Amendments of 1999”.

1 **SEC. 2. REPROCESSED MEDICAL DEVICES.**

2 Subchapter A of chapter V of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
4 ed by adding at the end the following:

5 **“SEC. 524. REPROCESSED MEDICAL DEVICES.**

6 “(a) FINDINGS.—Congress makes the following find-
7 ings:

8 “(1) The Food and Drug Administration has
9 information indicating that some reprocessed med-
10 ical devices labeled for single use have been associ-
11 ated with serious injury and that reprocessed med-
12 ical devices labeled for single use have the potential
13 to cause injury.

14 “(2) Reprocessed medical devices labeled for
15 single use are being used on patients without their
16 knowledge, against original manufacturers’ warn-
17 ings, and without a determination by the Food and
18 Drug Administration that such devices are safe and
19 effective.

20 “(3) The reprocessing of devices that are la-
21 beled for single use is currently occurring without
22 premarket approval by or notification to the Food
23 and Drug Administration, such as is required for
24 certain devices under sections 510 and 515.

25 “(4) The Food and Drug Administration should
26 have the knowledge and expertise to evaluate the

1 safety and effectiveness of reprocessed medical de-
2 vices labeled for single use.

3 “(5) Enforcement by the Food and Drug Ad-
4 ministration of the provisions of this Act that ad-
5 dress the safety and effectiveness of devices is the
6 only effective way to protect patients exposed to re-
7 processed medical devices labeled for single use.

8 “(6) The United States public deserves to know
9 that all devices regulated by the Food and Drug Ad-
10 ministration are safe and effective and that the ap-
11 propriate level of oversight is being implemented in
12 order to guarantee such safety and effectiveness.

13 “(b) PURPOSE.—The purpose of this section is to—

14 “(1) require that the Food and Drug Adminis-
15 tration implement all provisions of this Act that are
16 applicable to reprocessed medical devices, including
17 device registration, listing, and premarket safety
18 controls; and

19 “(2) require the informed consent of patients
20 prior to using reprocessed class II and class III
21 medical devices.

22 “(c) REGISTRATION.—Every person or establishment
23 engaged in the reprocessing of a device labeled for single
24 use shall—

1 “(1) upon first engaging in the reprocessing of
2 such device, register with the Secretary and provide
3 all information required in accordance with section
4 510(c);

5 “(2) for each year in which the person or estab-
6 lishment engages in the reprocessing of such device,
7 register with the Secretary and provide all informa-
8 tion required under section 510(b); and

9 “(3) for each year in which the person or estab-
10 lishment engages in the reprocessing of such device,
11 submit to the Secretary a list of devices labeled for
12 single use that the person or establishment is re-
13 processing, including the names of the original
14 equipment manufacturers of such devices and the
15 specific models of such devices that are reprocessed.

16 “(d) INFORMATION.—Every person or establishment
17 engaged in the reprocessing of a device labeled for single
18 use shall, for each reprocessed medical device, provide to
19 each person or establishment that uses such reprocessed
20 medical device, information necessary for such person or
21 establishment to comply with subsection (f).

22 “(e) SAFETY AND EFFECTIVENESS.—Every person
23 or establishment required to register under subsection (c)
24 with respect to a device shall demonstrate to the Secretary
25 that such reprocessed device is safe and effective or sub-

1 stantially equivalent to a device the Secretary has deemed
 2 safe and effective. The Secretary may exempt class I de-
 3 vices from the requirements of this subsection.

4 “(f) INFORMED PATIENT CONSENT AND MEDICAL
 5 RECORDS.—

6 “(1) IN GENERAL.—Every person or establish-
 7 ment that uses a class II or class III reprocessed
 8 medical device to provide medical care to an indi-
 9 vidual shall seek informed consent from the patient
 10 for the use of such a device.

11 “(2) MEDICAL RECORDS.—

12 “(A) IN GENERAL.—Every person or es-
 13 tablishment that uses a class II or class III re-
 14 processed medical device to provide medical
 15 care to an individual shall keep a record of such
 16 use and include a note of such use in such indi-
 17 vidual’s medical record.

18 “(B) CONTENTS.—The contents of the
 19 record described in paragraph (1) shall
 20 include—

21 “(i) the name and place of business of
 22 the person or establishment that reproce-
 23 ssed the device labeled for single use and
 24 the batch or lot number of such device;
 25 and

1 “(ii) the identity of the original manu-
2 facturer of the device.

3 “(g) REPORT.—Not later than 9 months after the
4 date of enactment of this section, the Secretary shall sub-
5 mit a report to the Committee on Commerce of the House
6 of Representatives and the Committee on Health, Edu-
7 cation, Labor, and Pensions of the Senate that describes
8 findings from current Food and Drug Administration
9 studies (as of the date of submission) on the safety and
10 efficacy of reprocessing of devices labeled for single use.

11 “(h) MEDWATCH.—Not later than 6 months after the
12 date of enactment of this section, the Secretary shall mod-
13 ify the MEDWATCH forms to facilitate reporting of infor-
14 mation relating to reprocessed medical devices, including
15 the name of a reprocessor and the number of times a de-
16 vice has been reused.

17 “(i) APPLICATION.—All other sections of this Act
18 that govern devices as defined in section 201(h) shall also
19 apply to reprocessed medical devices, if applicable.

20 “(j) DEFINITIONS.—In this section:

21 “(1) REPROCESSED MEDICAL DEVICE.—The
22 term ‘reprocessed medical device’ means a device
23 that—

24 “(A) is labeled for single use, or is dispos-
25 able and intended for single use; and

1 “(B) is cleaned or sanitized after use in
2 order that such a device may be reused upon
3 another individual.

4 “(2) REPROCESSING.—The term ‘reprocessing’
5 means a procedure employed in order to produce a
6 reprocessed medical device.”.

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